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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/711,886	10/12/2004	Yandong Jiang	022727-0117	5885
21125	7590	08/16/2005		
NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604				
			EXAMINER DOSTER GREENE, DINNATIA JO	
			ART UNIT 3743	PAPER NUMBER

DATE MAILED: 08/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/711,886

Examiner

Dinnatia Doster-Greene

Applicant(s)

JIANG, YANDONG

Art Unit

3743

Talm

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Detail Action.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 6, 7, 8, 10, 11, 13, 14, 17, 18, 19, and 24-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Bibi (U.S. Patent No. 6,371,112). Bibi discloses a system for maintaining an open airway, comprising a mouthpiece and a nasal mask. The mouthpiece adapts to form a substantially sealed cavity (col. 6, lines 5-10) within a patient's mouth and adapted to be coupled to a negative pressure generator (col. 1, lines 21-24) that is effective to create a negative pressure (cols. 7-8) within the substantially sealed cavity to prevent the patient's soft tissues of the upper airway from collapsing. The nasal mask (38) adapts to deliver gases through the patient's nasal passageway.

Regarding claim 2, 14, and 18, Bibi discloses wherein the mouthpiece is effective to form a substantially sealed cavity within the patient's mouth (col. 6, lines 58).

Regarding claim 5, 13, 24, and 25 Bibi discloses wherein the mouthpiece includes a hollow elongate member (24) extending therefrom and coupled to a negative pressure generator.

Regarding claim 6, Bibi discloses wherein the nasal mask is coupled to the mouthpiece (Fig. 3).

Art Unit: 3743

Regarding claim 7, Bibi further discloses a negative pressure generator (col. 1, lines 21-23 and cols. 7-8).

Regarding claims 8 and 15, Bibi discloses wherein the nasal mask is coupled to a device selected from the group consisting of a continuous positive airway pressure device (see, entire document), a mechanical ventilation device, and a positive end expiratory pressure device.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3, 12, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bibi in view of Kulick (U.S. Patent No. 6,494,209). Bibi discloses the claimed invention with the exception of specifically teaching without impinging on the tongue. However, Kulick, which also relates to a sleep apnea treatment device, teaches that it is

Art Unit: 3743

known to create a negative pressure in order to draw the tongue forward without impinging the user's tongue. Thus, it would have been obvious to one skilled in the art to design the mouthpiece 22 of Bibi so that it is capable of preventing the patient's soft tissue of the upper airway from collapsing without impinging on the user's tongue for the purpose of treating sleep apnea.

Claims 4, 21, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bibi in view of Thornton (U.S. Patent No. 6,405,729). Bibi discloses the claimed invention with the exception of specifically disclosing a mouthpiece including upper and lower portions that conforms to the patient's upper and lower dental structures. However, Thornton, which also relates to a sleep apnea treatment device having an oral and a nasal mask, discloses that a mouthpiece having upper and lower portions to conform to the patient's lower and dental structures is known in the art. Thus, it would have been obvious to one skilled in the art to incorporate the mouthpiece of Thornton into the device of Bibi for the purpose of increasing the user's comfort.

Claims 9 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bibi in view of Curti et al. (U.S. Patent Application No. 2005/0103347). Bibi discloses the claimed invention with the exception of specifically disclosing taking gas samples from the nasal passageway. However, Curti, which also relates to a sleep apnea treatment device having an oral and a nasal mask, discloses that it is known to include a tubular member to permit gas samples to be taken from the nasal passageway. Thus,

Art Unit: 3743

it would have been obvious to one skilled in the art to incorporate the gas sampling means of Curti into the nasal mask of Bibi for the purpose of enhancing the treatment and detection of sleep apnea as taught by Curti [0003].

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dinnatia Doster-Greene whose telephone number is 571-272-7143. The examiner can normally be reached on 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-7143.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ddg

Henry Bennett  
Supervisory Patent Examiner  
Group 2700

